Section III: The Future of Cancer Control and Prevention in New Jersey

Chapter 13: Emerging Trends

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CHAPTER 13. Emerging Trends

ACCESS TO CLINICAL TRIALS

Clinical trials are studies designed to answer a scientific question. This question may have been developed in carefully controlled laboratory research. Clinical trials are designed to bridge the gap between basic laboratory research and the patient by testing new treatments, investigating new means of prevention, improving early diagnosis, monitoring quality of life, and/or studying the psychological impact of cancer (1).

Clinical trial participants have historically been white with a middle or upper socioeconomic background. Researchers have long acknowledged the need to diversify clinical trial research (2). Barriers to inclusion of both culturally diverse patients and patients with lower socioeconomic status can be patient driven, physician driven, or system driven.

Many clinical trials have rigid inclusion criteria and complex testing regimes that can seem overwhelming to patients. Some patients feel that if they participate in clinical trials, they are no better than "guinea pigs"; others feel that only patients with no hope are placed on clinical trials. Patients may fear that participation in a clinical trial means being treated with an experimental therapy, or that they may not receive appropriate treatment, which may be a legacy of the Tuskeegee Syphilis Study (3). A patient may not have the resources needed to travel to and from testing and treatments or may fear that a clinical trial will not be covered by insurance. Patients who are not fluent in English may have difficulty understanding the consents and the commitment needed to participate in a clinical trial.

Physicians may be reluctant to place patients on clinical trials for a variety of reasons. They may lack knowledge of clinical trials available in their area. Clinical trials take time, and physicians are not always willing to complete the paper work necessary to place a patient on a trial. Many physicians fear that by referring a patient to another doctor for a clinical trial, they will lose the patient (4).

If we examine one small aspect of clinical trials, we can begin to understand some of the barriers to recruitment (5). Some clinical trials "randomize"; that is, the patient is assigned by chance to either the treatment or a control group. Many patients are uncomfortable with this. They want to be in charge of their care and do not want their treatment left to chance. Many physicians are biased toward a particular type of treatment or dislike the treatment designated for the control group, which may keep physicians from suggesting clinical trials. An inherent conflict also exists between the physician, the caregiver, and the research physician. The allegiance of the caregiver and the physician is to the patient, while the scientist physician places the potential benefit to humanity and future generations first (4). This is just one aspect of the clinical trial process. So it is clear there is no simple answer to the problem of inclusion in clinical trials.

Education across the range of people and systems involved in clinical trials is needed to ensure that all New Jerseyans have access to the best possible care, and that care is often available through participation in clinical trials. The researcher, the physician, and the patient must understand what clinical trials can do and how to make informed decisions about participating in them. Issues specific to clinical trials have, therefore, been addressed throughout the chapters in the *Plan.*

CANCER SURVIVORSHIP - CHALLENGES AND ISSUES FOR A GROWING POPULATION

"With communication comes understanding and clarity; with understanding, fear diminishes; in the absence of fear, hope emerges; and in the presence of hope, anything is possible."

Ellen Stovall, Survivor
National Coalition for
Cancer Survivorship (NCCS)

The American Cancer Society estimates the number of Americans who will receive a cancer diagnosis this year to be 1,268,000. Statistics estimate the number of expected deaths from cancer this year to be 553,400 (6). While these are staggering figures, progress is being made in increasing cancer survival rates. For example, according to SEER data, the overall five-year survival rate for adolescents with cancer improved from 69% to 77% from the period 1975-1994 (7).

Dr. Harmon Eyre, Executive Vice-President of the American Cancer Society states, "It is a testament to the success of the American Cancer Society and other such organizations, as well as the countless researchers and clinicians who engage daily in the ongoing battle against cancer, that there are about nine million cancer survivors living in the United States today." That is, the term cancer *victim* is being transformed into the term cancer *survivor* and includes representatives from all age groups (8). Yet the special needs of cancer survivors are not being adequately addressed. These needs include psychosocial needs, follow-up care, information needs, and legislative advocacy.

Psychosocial Needs. For most people, a diagnosis of cancer is an overwhelming experience. Fear of dying, worry about medical treatments, and concern over role changes at home or at work can make people feel isolated and alone at a time when they most need others. Finding someone to talk to and share experiences with can ease the sense of isolation and reduce the stress (11). Since the psychosocial needs that arise from living through the cancer experience are not uniformly met in the healthcare system, more and more people with cancer are seeking groups to help them cope.

Realizing that others have experienced reactions and fears similar to their own reassures survivors that their reactions are normal. Research (9;10) underscores the positive effects of group participation on coping and on people's own evaluation of their quality of life. Some of this research also suggests that group participation increases post-treatment survival (11-13).

Existing support programs need to be continued, and new deliveries created, in response to the unique needs of survivors. In part this support is provided in groups – peer support – shared experience(s); educational programs delivered in the community or via toll-free teleconferences – facilitating learning and coping; website support through participation in chat and discussion groups; listening to and sharing personal stories; and accessing state of the art information, recommended books, and articles.

Follow-up Care. As we move into the 21st century, we are faced with an increasing number of childhood cancer survivors who are living into their middle adult years and beyond. Providing appropriate comprehensive follow-up care is a challenge for healthcare providers and one that can be met by developing quality follow-up programs for all childhood cancer survivors (14).

The future challenges and needs of survivorship for adult and child populations should address the impact of the lifetime effects of a cancer diagnosis. For example, who should monitor these various aspects of

survivorship - the primary care physician or the oncologist? Cancer treatment modes can and do affect other organ functions during survivorship. Survivors should be monitored continually during their lifetime to help reduce the chances of recurrence and late-term effects of treatments. Some examples include: fatigue, depression, psychosocial problems, and sexual dysfunction.

We should include a broader community service commitment to meet the needs of cancer survivors, concentrating on wellness and health maintenance issues rather than treatment. In fact, communities should be encouraged to create programs to address the needs of cancer survivors as contributing members of the community and include new and existing community support systems within the State of New Jersey.

Information Needs. Other survivorship services should include faster distribution and promotion of cancer resources to healthcare providers and to the public. The amount of new research data being generated is staggering, and our knowledge is constantly changing at a rapid pace. A dialogue between the media and healthcare representatives should be encouraged to help promote news of the latest in cancer treatment other survivorship issues for this population. Although researchers have begun to tackle these issues, the gaps in knowledge of the long-term effects of surviving cancer can be frustrating to survivors themselves and to their practitioners (15).

Childhood survivorship issues for the future must include better access to high-quality medical care in combination with a strong medical model concentration on wellness and prevention. Again, these wellness management issues should include ongoing dialogue between the primary care physician and the oncologist. Individualized cancer wellness programs need to be continually developed and fine-tuned to meet the challenges of legal, psychosocial, emotional, and late-term treatment effects of the patient. For example, lifestyle choices such as nutrition, weight management, exercise, and reduced stress management have been proven to contribute to quality of life, along with positive approaches to living a more productive life.

Legislative Advocacy. Finally, legislative support for quality care issues is essential if quality of life is to be maintained throughout the lifetime of the survivor. In 1998, legislation was passed earmarking $15 million for the National Cancer Institute to better understand the issues cancer survivors face. Appropriations must continue and grow to meet research demands and provide necessary tools to the medical and survivor communities. For example, according to American Cancer Society data for 1999, 16% of Americans under 65 have no health insurance and about 26% of older persons have only Medicare coverage; 18% of Americans aged 18 to 64 years do not have a regular source of healthcare.

There is a critical need to understand the issues of the growing survivor population. Existing and future outreach into research and partnerships will be essential for the collection of data and for programming efforts within New Jersey as well as from all across the country.

In summary, cancer survivorship concerns are myriad. The cancer experience will continue to challenge this population to regain control over their lives and to expect “a time of life as usual.” It is critical that we understand the issues and provide resources for this ever-growing population. We must continue to provide the education, resources, and tools for self-advocacy and ensure a high quality of life (16).

COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) - ITS EFFECTS ON CANCER TREATMENT

Complementary and alternative medicine (CAM) cannot be overlooked by conventional medicine. CAM is being used by a significant proportion of the U.S. population for therapy as well as for health promotion and disease prevention. Not only have surveys documented CAM's widespread use, but also its increasing use in the past decade. Using the results of a population-based survey, Eisenberg et al. extrapolated that in 1990 an estimated 61 million Americans used at least 1 of 16 unconventional therapies and approximately 22 million Americans saw providers of unconventional therapy for a principal medical condition. Repeating this survey in 1997 found that the use of 1 of 16 alternative therapies during the previous year increased from 34% in 1990 to 42% in 1997. Further, this increase was attributable primarily to an increase in the proportion of the population seeking alternative therapies, rather than increased visits per patient (17;18).

CAM has been defined as medical interventions not taught widely at U.S. medical schools or generally available at U.S. hospitals (17). However, this definition may no longer be satisfactory, since some forms of CAM are now taught in medical schools, and hospitals and health maintenance organizations now offer it (19). Laws in some states require that health plans cover it (20). CAM is identified with the following types of therapies: acupuncture, biofeedback, chiropractic, commercial weight-loss programs, energy healing (including magnets), folk remedies, herbal medicine (including teas), homeopathy, hypnosis, imagery, lifestyle diets (e.g., macrobiotics), massage, megavitamins, relaxation techniques (including meditation), self-help groups, and spiritual healing. Cited as the types of therapy most used are relaxation techniques, herbal medicine, massage, and chiropractic. In both surveys referenced above, as well as others, respondents cited the following conditions that accounted for the most frequent use of CAM therapies: chronic conditions, including back problems, anxiety, depression, and headache. Also cited were chronic fatigue, muscle sprains, arthritis or rheumatism, digestive problems, and diabetes. Cancer was included in the 1990 survey among the conditions for which CAM therapies were most frequently used, but not in 1997 (17;18;21).

The funds expended for CAM have also increased and are significant. The estimated expenditures for alternative medicine professional services increased over 45% between 1990 and 1997 and were conservatively estimated at $21.2 billion in 1997, with at least $12.2 billion paid out of pocket. Total 1997 out-of-pocket expenditures relating to alternative therapies were conservatively estimated at $27 billion, which is comparable with the projected 1997 out-of-pocket expenditures for all U.S. physician services (17;18).

The reasons why people with cancer use CAM are multiple. Many are likely to do so when conventional therapies no longer offer the possibility of cure or remission. Others seek CAM out of fear of chemotherapy, surgery, and radiation, the most common conventional therapies. For some tumor systems, no conventional therapy exists or there are experimental clinical trials whose outcome is unknown. It has been suggested that cancer patients may feel a loss of control that leads them to use CAM as a way to regain or exercise some control over their care and that they achieve a sense of contributing to the care of their malignancy (21-23).

Studies have shown that persons using CAM tend to be better educated and hold a philosophical orientation toward health that can generally be characterized as holistic, e.g., they believe in the importance of body, mind, and spirit in health. Users of alternative healthcare are also more likely to report poorer health status than nonusers. However, users of CAM are reported to be no more dissatisfied with or distrustful of conventional care than nonusers (22).

Of respondents to the Eisenberg et al. survey done in 1990, 83% reported having one or more principal medical conditions, and close to 60% of these with at least one principal medical condition saw a medical doctor but not a provider of unconventional therapy; 3% saw only a provider of unconventional therapy; 7% saw both a medical doctor and a provider of unconventional therapy; and 33% saw neither for at least one principal medical condition (17).

Among respondents in the 1990 survey who reported a principal medical condition and used unconventional therapy for that condition, only 4% saw a provider of unconventional therapy without also seeing a medical doctor. No respondent saw a provider of unconventional therapy but not a medical doctor for the treatment of cancer, diabetes, lung problems, skin problems, high blood pressure, urinary tract problems, or dental problems (17). However, Gertz, in an article published in 2001, states that it is estimated that fewer than one-half of patients with cancer receive only conventional therapy; approximately 44% combine conventional and alternative methods; and 10% of patients with cancer use unorthodox therapy only and forgo any form of conventional anticancer treatment (21).

Close to 90% of respondents who saw a provider of unconventional therapy in 1990 did so without the recommendation of their medical doctor. More than 70% of users of unconventional therapy did not inform their medical doctor of this use. This pattern of nondisclosure persisted in the 1997 survey (17;18).

This lack of disclosure can have serious consequences for cancer patients and others. Because vitamins and herbs are considered to be nutritional supplements, they are unregulated by the U.S. Food and Drug Administration. This permits a lack of quality control in the products, and misleading labeling that can lead to patients thinking they are taking a certain amount, when in reality they are receiving excessive amounts of potent or harmful substances. For example, the herbal combination PC-SPES, containing eight herbs, has potent clinical effects in-patients with prostate cancer. This product is considered a dietary supplement and can be found in many health food stores. Because of the need for close monitoring and regulation of dosage, it is not recommended that patients use PC-SPES outside clinical trials (23). Other examples cited in the literature are of patients receiving chemotherapy or radiation who consume herbs, high-dose vitamins, or supplements before or during treatment. These substances may, hypothetically, inhibit or enhance the activity of conventional therapeutic agents. Further harm can be done when substances such as shark cartilage, bee pollen, and vitamin E affect laboratory studies, such as transaminase, used to monitor malignancies (22;24).

It is because CAM, for the most part, lacks scientific evidence for safety and efficacy, as required by the FDA for the approval of drugs and by peer-reviewed medical journals for the publication of research reports, that medical authorities set it apart (25). Although most CAM therapies are relatively low risk, any therapy that results in a delay of a proven

therapy indirectly causes harm. An example of this is a recommendation against a biopsy of a potentially malignant site by a promoter of analysis of heavy metals in the blood, hair or nail analysis, and iridology. Particularly troublesome to conventional providers are the alternative therapies that espouse a simple etiology to explain all cancers. This thinking progresses to include using natural methods to treat cancer and cites the role of the bowel in contributing to malignant disease (21). It is generally agreed that there is inconclusive evidence about the safety, efficacy, mechanism of action, and cost-effectiveness of individual alternative treatments (22;24). Exceptions to this premise include the use of spinal manipulation for acute low back pain, acupuncture for nausea, and behavioral and relaxation techniques for chronic pain and insomnia (26-28).

A systematic analysis of published articles on CAM was performed on reports of trials, surveys, and systematic and traditional reviews. This analysis excluded articles of a subjective nature, such as editorials, commentaries, and book reviews and indicated that there is a "relative paucity of evidence from randomized controlled trials and systematic reviews…". More studies are needed in order to make informed decisions on the value of integrating CAM into conventional healthcare (29).

It is expected that as the public's interest in CAM increases, the numbers of conventional schools offering courses in CAM will continue to grow. Centers in medical schools and schools of public health to study CAM are also being established (30;31). The Office of Alternative Medicine, renamed the National Center for Complementary and Alternative Medicine, under the auspices of the National Institutes of Health, was established in 1992. This Center is making headway in funding studies that evaluate unproven treatments for cancer.

The public is increasingly exposed to information about CAM and conventional treatments through direct-to-consumer (DTC) advertising in the media and on the web. Although the reliability of the public information received through these sources is not always known, an argument put forth by the pharmaceutical industry is that DTC advertising encourages patients to take more questions to their doctors, and this may be a benefit rather than a disadvantage. Another argument for receiving information through the lay media or advertising is that it encourages patients to become partners in their own healthcare (32).

As the public becomes increasingly aware of both conventional and CAM modalities, healthcare providers should include asking their patients about their use of CAM. In order to safeguard the patients' health, these questions should be asked during the initial history taking and should be repeated at regular intervals. For cancer patients, this information can be critically important as it can reveal that the patient is taking herbs or other substances that may interfere with conventional therapy or alter laboratory values. The conventional provider may also be a source of information on CAMs that are not harmful and can offer the cancer patient a level of comfort not achieved by conventional therapy alone.

INFECTION AND CANCER

EPSTEIN-BARR VIRUS

Epstein-Barr virus (EBV) is a human herpes virus. It is the etiologic cause of infectious mononucleosis and is associated with several malignancies. EBV has been strongly associated with nasopharynegeal carcinoma (NPC) and Burkitt's lymphoma (33). There are varying degrees of evidence linking EBV to Hodgkin's disease, gastric carcinoma, lung carcinomas, and neoplasms of smooth muscle origin (34). It has long been suspected that EBV acts in concert with other co-factors in the development of cancer, but those putative co-factors currently remain unidentified (33). Alternatively, it has been suggested that EBV is reactivated during the course of development of some of these tumors, and thus that EBV may merely be a marker rather than have any etiologic relationship.

Non-keratinizing NPC, especially the undifferentiated type, is closely associated with EBV. While this cancer is common in South East Asia, Alaska (among Eskimos), and North Africa, it is rare in Western countries with an annual incidence of less than 0.5 cases per 100,000 (34). In geographic regions of high squamous cell NPC incidence, the proportion linked with EBV is high. In contrast, in low NPC incidence regions, a low proportion are linked with EBV. It is important to note that another infectious agent, human papillomavirus (HPV), has been implicated in the pathogenesis of squamous cell NPCs (34). Proposed risk factors for development of NPCs include exposure to salted fish at an early age and certain tumor-producing compounds, such as nitrosamines, which are found in some food products (35). Further, smoking has been established as a major risk factor for development of squamous cell NPCs (but not of non-keratinizing NPCs). It has been suggested that smoking may account for up to two-thirds of squamous cell NPCs (34).

Burkitt's lymphoma (BL), a high-grade lymphoma of B cells, is commonly found in equatorial Africa and New Guinea. However, it occurs sporadically in other areas of the world (36). Over 95% of BL cases in Africa are associated with EBV, but only 20% to 30% of cases in the U.S. demonstrate an association (36). Baumforth and others have hypothesized that perhaps the low percentage of EBV-associated cases in the U.S. is related to a loss of EBV at some point in tumor development (35).

Approximately 10% of gastric carcinoma cases (e.g., more than 50,000 cases per year) worldwide have EBV integrated into the cancer cells. Germany (18%) and the U.S. (16%) have the highest proportions of gastric carcinomas positive for EBV (37). A study involving a Japanese population reports that the incidence of EBV-positive gastric carcinoma is three times higher in men than in women and is higher for younger men (37).

The development of Hodgkin's disease, a relatively uncommon cancer in the U.S., has long been thought to be associated with EBV. It has been reported that when compared to persons without a history of infectious mononucleosis, persons with a history of infectious mononucleosis have a two-to-five-fold increased risk of developing Hodgkin's disease (38). In addition, EBV has been detected in up to 50% of Hodgkin's disease cases in Western nations and in up to 100% of pediatric patients (39).

It has been suggested that EBV may be involved in the pathogenesis of various other cancers as well. EBV is found in cases of non-Hodgkin's lymphoma (NHL) of the peripheral T cell type. A consistent

Association has been described between EBV and nasal angiocentric T/NK-cell lymphoma (39). Lymphoepithelial carcinoma of the salivary gland, a relatively uncommon tumor, is most prevalent in Eskimos and Southern Chinese populations and is associated with EBV. While past cases of Caucasian patients have not demonstrated association with EBV, newer cases have been reportedly associated with EBV (36). EBV may be involved in the development of oral squamous cell carcinomas, especially since a proportion of patients with the disease do not smoke or consume alcohol (36). EBV has been associated with lymphoepithelioma-like carcinoma of the lung in Asian populations, but not in Western patients (40). The first report of an EBV-associated smooth muscle tumor of the kidney occurred in 1998 (41). EBV-associated smooth muscle neoplasms arising at other locations have been reported previously in patients with AIDS and in recipients of organ transplants (41).

Currently there are no therapies or vaccines available for EBV. Since several anti-herpes agents are presently available, it is likely that EBV-specific agents will be developed at some point (36).

In the future, if national clinical trials of treatments for EBV-positive gastric carcinoma commence, we should encourage participation in these trials of New Jersey institutions and of persons at risk and consider enhancement of support. Additionally, if national clinical trials of a vaccine for EBV commence, we should encourage participation and consider enhancement of support. As smoking appears to further increase the risk form Epstein-Barr virus for the development of squamous cell nasopharynegeal carcinoma, smoking cessation efforts should be strongly reinforced.

CANCERS ASSOCIATED WITH THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) EPIDEMIC

The acquired immunodeficiency syndrome (AIDS) pandemic has been associated with cancer essentially from the outset (42-45). The human immunodeficiency virus (HIV) is the etiologic cause of AIDS (46). HIV has been implicated in the increased incidence of several cancers. In addition, with the advent of more effective anti-retroviral therapies and improved supportive care, many persons are living longer with their HIV infection. Due to lengthening lifespans and their attainment of older ages at which cancers tend to begin occurring, AIDS patients are now developing malignancies that are not necessarily related to their HIV status. The underlying immunosuppression due to HIV, however, often greatly complicates standard therapeutic cancer approaches. For example, susceptibility to infections is greatly increased, often necessitating reductions in the standard therapeutic doses. Bleeding complications are also more common.

Persons at risk for HIV may also place themselves at increased risk from other environmental exposures. For example, many HIV patients are also injection drug users (IDUs) and often use multiple illicit substances, for which they receive counseling and therapy. Some HIV patients also enter alcohol treatment programs. However, although most IDUs also smoke, this has not generally been perceived to pose a major health threat, so counseling on smoking and smoking cessation components within substance abuse treatment programs are rare. Yet data suggest that smoking tobacco is the drug that in fact increases these individual's mortality and cancer risk (47), which raises the issue that smoking cessation programs need new emphasis among IDUs (47). Furthermore, both sexual and parenteral

exposures put persons who are at risk for HIV also at increased risk for infection with other agents associated with specific cancers.

The first tumor recognized in association with AIDS was Kaposi's sarcoma (KS). After the discovery of HIV, epidemiologic data suggested that in addition to HIV, a second infectious agent ("agent K") (45) might be involved (48). Although a herpes-like virus was linked with Kaposi's as long ago as 1972 (49;50), it was not until the AIDS epidemic that a specific agent, now called both human herpes virus type 8 (HHV-8) and a Kaposi's-associated herpes virus (KS-HV) was discovered (51;52). Almost all HIV-associated KS has occurred among men who have sex with men (MSMs). However, the evolving epidemiology of HHV-8 has demonstrated evidence of this virus in other risk groups, so the puzzle remains partially unresolved.

Non-Hodgkin's lymphoma (NHL), including primary brain lymphomas, also emerged early on as linked with the AIDS epidemic. The Epstein-Barr virus (EBV) may be involved in the pathogenesis. Although many HIV-infected young adults have been diagnosed with Hodgkin's disease, the high incidence of Hodgkin's lymphoma in young adults has led to uncertainty and controversy as to whether or not it is linked to the HIV epidemic.

In 1993 the Centers for Disease Control and Prevention (CDC) definition of AIDS, for the purposes of United States surveillance, newly include the occurrence of invasive cervical cancer (ICC) in an HIV-infected woman as a sufficient condition (53). The change was supported by data strongly linking cervical dysplasia with HIV infection (54), and by the finding by one group in New York City of an association with ICC (55). Thus, since that time, any woman infected with HIV who has ICC is automatically defined as having AIDS (56). This led to an increase in the number of women defined as having AIDS, especially in New Jersey (57). However, later data has raised some questions about the nature of the association (58;59). Anal carcinoma and squamous dysplasia both appear to have increased among MSMs. Both anal carcinoma and cervical carcinoma are strongly associated with certain types of human papillomavirus (HPV). It has been difficult to fully untangle the complex relationships, in part because some of the factors placing persons at risk for HPV are also risk factors for HIV acquisition. The role of screening for anal cancer and dysplasia in MSMs and others at high risk warrants further clarification (60;61).

The New Jersey Department of Health and Senior Services recently reviewed the New Jersey experience concerning the occurrence of cancers among persons with AIDS (59). This report serves as a comprehensive overview of the AIDS-related issues in New Jersey and provides relevant statistics. Data from the University of Medicine and Dentistry of New Jersey-University Hospital cancer registry (62;63) indicate increased lung cancers among HIV-infected patients compared to other cancers. Other studies, both from the U.S. and abroad, have also raised the issue of lung cancer and AIDS (59;64-67).

A prospective cohort study in New Jersey of men and women at high risk for HIV was begun in 1984 (68). The increased risk of lung cancer (69), when examined in terms of New Jersey yearly incidence data by age, gender, and race for lung cancer (70), remains: 8.4 fold increased in HIV+ compared to expected, 2.7 fold increased in those HIV negative. The 3.1 fold higher rate among HIV+ within the cohort was not attributable to increased smoking of tobacco or other products. These are the first cohort

data to suggest an increase in lung cancer among HIV-infected persons, thereby raising the possibility that lung cancer may emerge as a problem as HIV-infected persons age and also survive longer with the therapeutic advances in HIV care.

Human T-cell lymphotropic virus type I (HTLV-I) is causally associated with an aggressive leukemia and lymphoma syndrome (71-74), as well as with neurologic disease. Both HTLV-I and human T-cell lymphotropic virus type II (HTLV-II) are associated with immunologic abnormalities (75-78). It remains uncertain whether HTLV-II is linked to an increased risk for cancer (79). HTLV-I is uncommon in New Jersey except in people born in the Far East and the Caribbean. HTLV-II is common in New Jersey injection drug users (80;81). Current screening of blood donors has nearly eliminated the former risk of transfusion-related acquisition.

Hepatitis B and C viruses are discussed in the section on liver cancer. Human papillomavirus is discussed in further detail in the section on cervical cancer and below.

Steps that can be taken in the future to address issues in HIV and cancer include: monitoring cancer incidence trends in New Jersey among persons at increased risk for HIV and among those with HIV-infection; encouraging development of clinical trials that seek to improve survival in HIV-infected persons diagnosed with a malignancy; encouraging recruitment of persons for these trials, in light of many eligible persons being from groups that are historically less likely to participate in trials; continuing epidemiologic studies examining the risks for cancer among HIV-at-risk groups, including support for efforts exploring whether there are predictive markers or co-factors; continuing emphasis on providing integrated healthcare services to persons at HIV risk, including the routine provision of gynecologic screening services on site at primary healthcare settings, drug treatment programs, and AIDS clinics (54); and, develop programs targeted to IDUs to reduce excessive use of tobacco products.

HELICOBACTER PYLORI

Helicobacter pylori, a type of bacteria that colonizes human stomachs, has been associated with an increased risk for development of peptic ulcer disease and gastric cancers, in particular non-cardia gastric adenocarcinoma and gastric non-Hodgkin's lymphomas of B cell type (82). In 1994, the International Agency for Research on Cancer classified *H. pylori* as a group I carcinogen (e.g., as a definitive human carcinogen) for its role in gastric cancer development (83). Patients with chronic atrophic gastritis tend to have a particularly high risk of developing gastric carcinomas (83). There is also evidence of a strong association between *H. pylori* and gastric mucosal-associated lymphoid tissue (MALT) lymphoma. Since eliminating *H. pylori* often leads to MALT lymphoma regression, U.S. and European consensus conferences on *H. pylori* have recommended anti-bacterial treatment in cases of low-grade MALT lymphoma (83). In contrast, there is no evidence that, once other gastric cancers have developed, treatment of *H. pylori* infection per se changes the natural history of those cancers. Individuals with *H. pylori* colonization, especially by cytotoxin-associated gene-A-positive (CagA+) strains, may also have an increased risk for developing pancreatic cancer (84).

Meta-analyses have reported that *H. pylori* infection increases risk two-fold for gastric cancer development (85). More specifically, *H. pylori* infection is associated with a nearly six-fold increased risk of developing non-cardia gastric cancer (86). However,

H. pylori infection does not increase the risk for development of cardia gastric cancer. Current topographic codes permit description of the primary localization of the cancer within the stomach, when this can be determined. These data suggest that coding for the specific topography of gastric cancer in data routinely submitted to the New Jersey State Cancer Registry would be useful, given that *H. pylori* infection is associated with the non-cardia gastric cancers, to assess trends with respect to *H. pylori*-related cancers. While this coding scheme already exists, specific research efforts would be needed to assess the extent to which it is being properly abstracted, coded and submitted, and to assess whether efforts to improve the data quality and/or completeness should be undertaken. It is likely that standard reports from clinicians may not currently enable registrars to attain this degree of specificity with regard to the place of origin within the stomach.

The most highly studied types of *H. pylori* have been Cag+ strains, which account for 40% to 60% of strains in the Western world (i.e. western Europe, the U.S., and Latin America), and "most" of the strains in East Asia. Cag+ colonization is significantly associated with ulceration, gastritis, and gastric adeno-carcinoma in the Western world (82).

It has been hypothesized that the cohabitation of humans and *H. pylori* for millions of years implies that some type of symbiotic relationship may exist (82). In recent years, the prevalence of *H. pylori* has been declining. Factors contributing to the decline likely include: 1) lower birth rates (risk factors for colonization include early childhood crowding), and 2) increased antibiotic utilization (82). The fall in *H. pylori* colonization has been mirrored by a decrease in the incidence of gastric cancers. However, there have been increasing rates of various esophageal diseases (i.e. gastro-esophageal reflux or GERD, Barrett's esophagus, and adenocarcinomas of the lower esophagus) as well as gastric cardia adenocarcinomas (82). Blaser has speculated that there may be potentially protective effects of *H. pylori*, especially of Cag+ strains, and that perhaps the declining prevalence of *H. pylori* and increased rates of GERD and reflux esophagitis are related to *H. pylori* elimination. *H. pylori*-associated gastritis tempers gastric acid secretion; so eradication of the bacteria may lead to localized increased acid production and subsequent reflux esophagitis (87). Infection with Cag+ strains is significantly associated with a reduced risk for adenocarcinomas of the esophagus and gastric cardia (88). These results suggest that eradication of *H. pylori* may be harmful, as protective effects may be lost.

Smoking has been associated with a three-fold increase in the risk of gastric cancer. There is evidence of a much higher risk for non-cardia gastric cancer among smokers with *H. pylori* infection. As compared to uninfected non-smokers, smokers infected with CagA-negative *H. pylori* strains have a nine-fold increased risk in developing non-cardia gastric cancer, while smokers infected with CagA+ *H. pylori* strains have a 17-fold increased risk for non-cardia gastric cancer (89).

A well-documented risk factor for developing gastric cancer is a family history of this cancer, in the range of 1.5-to 3-fold (90). In addition, as compared with uninfected individuals with no family history, individuals with positive family history and infection with the CagA+ *H. pylori* may have a 16-fold risk of noncardia gastric carcinoma (90).

The theory of intrafamilial clustering of *H. pylori* infection is supported by evidence of *H. pylori* colonization in the parents and siblings of infected children (91). A strong association exists between the *H. pylori* infection status of parents and preschool-age children, suggesting that transmission may occur from parent to child. Specifically, as compared to children with uninfected mothers, preschool-age children of mothers infected by *H. pylori* have an almost eight-fold risk of being infected. As compared to children with uninfected fathers, children of infected fathers have nearly a four-fold risk (92). Further, infected individuals of higher birth order or from larger families may be at increased risk for developing gastric cancer (93).

While the prevalence of *H. pylori* in children may be less than 10%, more than one-half of children in poor socioeconomic conditions may be infected (94). It has been estimated that about 1% of infected children will develop gastric cancer. Thus, the risk for developing gastric cancer in children is limited. The multi-factorial basis of gastric cancer development (e.g., *H. pylori* infection, smoking, family history, vitamin C deficiency, etc.) further complicates the issue of screening and treatment. Generalized population screening has not been shown to be beneficial or cost-effective. Imrie has suggested that, once an effective vaccine for *H. pylori* is developed, vaccination might be considered for reducing gastric cancer (94).

Use of vitamin C has also been suggested as a preventative measure, because it may help to prevent gastric cancer by inhibiting the formation of *N*-nitroso compounds in gastric juice, destroying reactive oxygen metabolites in the stomach, and possibly inhibiting *H. pylori* infection (95). Since data are currently insufficient to support this approach, controlled trials will be needed to assess the positive and negative effects of vitamin C.

H. pylori eradication may be a treatment option, especially among individuals at high risk for developing noncardia gastric cancer. Currently, regimens such as triple antimicrobial therapy - a therapy that may include bismuth, metronidazole, and tetracycline (96) as well as other equally effective combinations, such as esomeprazole, clarithromycin, and amoxicillin (97) - have been used to effectively treat over 80% of *H. pylori* infections in patients with peptic ulcer disease. However, neither routine screening for *H. pylori* nor empiric treatment in the absence of active disease are currently recommended. Fendrick estimates that *H. pylori* screening may remain cost-effective at rates of cancer risk reduction of less than 30% (98). However, controlled studies are needed to prospectively confirm, and determine the amount of, noncardia gastric cancer risk reduction associated with *H. pylori* eradication. In addition, the benefits of *H. pylori* elimination should be weighed against a loss of its possible protective effects against esophageal disease. Until benefit is clearly established, the issue of cost-benefit remains moot. An indirect strategy for reducing the risk of developing gastric cancer may involve an intervention that prevents the progression from chronic atrophic gastritis to gastric cancer (98).

Future considerations should include: 1) emphasizing smoking cessation programs; 2) considering support for clinical trials that screen for H. pylori among persons at high risk (e.g., smokers and persons with a family history); 3) if national clinical trials of the efficacy of vitamin C commence, encouraging participation of New Jersey institutions in these trials among persons at risk; 4) providing funding for a research study led by

cancer epidemiologists in conjunction with local cancer registrars and the New Jersey State Cancer Registry to examine the extent to which gastric cancer subtype information (e.g., cardia versus non-cardia gastric cancer) is being collected, its adequacy and the feasibility for improvement, and assess its utility for prospective surveillance. This study should be undertaken in the near term, before further advances in therapy or the development of a vaccine for H. pylori, so that adequate baseline data may be assessed.

HUMAN PAPILLOMAVIRUS

Human papillomaviruses (HPVs) are DNA viruses that have been associated with the development of warts and a variety of cancers. HPVs can be separated into three categories based upon the risk of malignancy: low risk (including types 6, 11, 42, 43, 44), intermediate risk (including types 31, 33, 35, 51, 52, 58), or high risk (including types 16, 18, 45, 56) (99). Low-risk types are associated with benign lesions, which rarely become malignant, while intermediate-risk types are found in high-grade intraepithelial lesions. High-risk types are associated with intraepithelial and invasive cancers (99).

HPVs are very strongly linked to cervical cancer (100). HPVs are also associated with oral squamous cell carcinoma (OSCC), anorectal dysplasia and cancer, naso-pharyngeal carcinoma (NPC), esophageal cancer, and squamous cell carcinomas of the larynx, vulva, and penis. HPV is transmitted by close contact of skin or mucosal surfaces to an infectious source. Genital HPV infection is sometimes observed in young children and among persons who deny ever having had sexual contact, raising the question whether transmission from environmental surfaces or transplacental transmission may sometimes take place (101).

Cervical cancer is the second most common cancer among women worldwide. In the U.S., the incidence of cervical cancer is nearly 9.8 per 100,000 women. Of the 15,700 new cases diagnosed annually, 4,900 result in death (102). The mean age for developing cervical cancer is 52, and the frequency of cases is highest for women 35-39 and 60-64 (103). While HPV (especially types 16 and 18) is the most strongly associated etiologic cause of cervical cancer, other factors such as smoking, tar-based vaginal douching, oral contraceptive use, inadequate nutrition (e.g., insufficient vitamins A, C, and E), age at first intercourse, number of partners, and possibly HIV or herpes simplex virus type 2 infection may be involved (102). Further, HPV infection is independently associated with number of sex partners, oral contraceptive use, younger age, and black race (104). Almost 90% of cervical cancers worldwide are attributed to HPVs, and HPV type 16 accounts for one-half of these cases (105). HPV type 16 predominates in squamous cell tumors, while HPV type 18 predominates in adenocarcinomas and adenosquamous tumors (105).

The mainstay for screening for cervical cancer in the United States has been the Papanicolaou ("Pap") smear, a test that involves examining cells collected from the vagina and cervix for cancer detection. The American Cancer Society and the American College of Obstetricians and Gynecologists have recommended pelvic exams and Pap smears for women beginning at age 18 (99), and other groups additionally recommend screening for any woman who is, or may be, sexually active (106), independent of her partner's gender(s) (54;107). Annual screening has been common practice in the United States for many years, although evidence to suggest that outcomes are substantially better with annual than with

biennial or triennial screening is limited at best (106). Although the screening interval may now be somewhat controversial, the need for regular screening is not. There still remain major gaps in New Jersey in the delivery of routine gynecologic care, including screening (54;108). The advent of newer methods of HPV detection and innovations in cervical cancer screening, including ThinPrep Papanicolaou tests, are leading to reassessment of screening guidelines (106).

Vulvar carcinoma has been associated with HPV infection, but this association is not as strong as it is for cervical cancer. The highest incidence of vulvar carcinoma occurs at age 80, and most women with this cancer are between the ages of 65 and 80 (109). It has been reported that up to 60% of vulvar carcinomas may be associated with HPV, but results vary depending on the method used for detecting HPV (110). HPV type 16 is the predominant type found among the cases of vulvar carcinoma (110).

Penile cancer is rare in the Western world with an incidence of less than 1 per 100,000. Common risk factors for penile cancer include phimosis, lack of circumcision (although this has recently again become controversial), balanitis, lichen sclerosus et atrophicus, smoking, UV light irradiation, number of sexual partners, and HPV infection (111;112). Approximately 40% of penile cancer cases are associated with HPV, and HPV type 16 is the predominant type found in these cases (111).

Anal dysplasia is common in biopsy specimens from homosexual men with visible HPV-associated internal anal abnormalities. Natural history studies are needed to better determine the clinical significance of anal dysplasia, rates of progression to cancer, and the role of screening and therapy (60;113). Women who have anal sex may also be at increased risk for anorectal dysplasia (114).

Oral cancer, a common cancer in the U.S. (e.g., over 30,000 cases diagnosed each year), leads to 7,800 deaths per year (115). Risk factors for OSCC, the most common type of oral cancer, include diets low in fruits and vegetables, smoking, and alcohol consumption (116). Recently, HPV has been suggested as a possible risk factor for OSCC. One meta-analysis suggests that HPV is more than five times more likely to be detected in patients with OSCC than in patients with normal, noncancerous oral mucosa (115). Furthermore, up to 60% of OSCC cases may be associated with HPV infection (116). Specifically, HPV types 16 and 18 were present at higher rates than other HPV types among patients with OSCC (116).

Laryngeal cancer, which accounts for 1.2% of cancer cases in the U.S., may be associated with HPV. More than 90% of laryngeal cancers are squamous cell carcinomas (SCCs). Risk factors for laryngeal cancer include alcohol and tobacco use (117). HPV type 16 was the most commonly found type in patients with laryngeal cancer. However, there are no definitive data concerning the percentage of laryngeal SCCs associated with HPV (117). Estimates vary from 8% to 54% (117).

Esophageal cancer is known to be caused by smoking and alcohol consumption, but there is conflicting data concerning its association with HPV (118). Nearly 287,000 deaths due to esophageal cancer occur each year. Incidence of this cancer is higher among men (118). Several studies have suggested that an association exists between HPV infection and development of esophageal cancer. HPV types 16 and 18 are detected at higher rates in patients with esophageal SCC, and HPV type 16 has been associated with an increased risk

for esophageal cancer (119). However, Lagergren has recently reported that infection with HPV types 16 or 18 is not associated with higher risk for esophageal adeno-carcinoma or esophageal SCC (118).

Nasopharyngeal cancer (NPC) is a relatively uncommon cancer with a worldwide incidence of 1 in 100,000, but the incidence is higher in certain areas, such as Southeast Asia and North Africa (120). The possible relationship between EBV and squamous cell NPCs is not fully clear (see section on EBV). There is evidence of an association between HPV and squamous cell NPCs. Preliminary findings suggest that up to 50% of NPC cases in American Caucasians may be associated with HPV (120). Proposed risk factors for development of NPCs include exposure to salted fish at an early age, nitrosamines (which are found in some food products), and smoking (35). Smoking may account for up to two-thirds of all squamous cell NPC cases (34).

Recommendations with respect to specific cancers noted above, and especially regarding cervical cancer, may be found in their respective chapters.

LIVER CANCER

Primary liver cancers are any malignant tumors that arise in the liver itself, as opposed to having metastasized to the liver. The most common types are hepatocellular carcinoma (HCC) and cholangiocarcinoma, which arise from the liver cells and the bile ducts, respectively (121). Cases are usually rapidly fatal.

Infection with either hepatitis B virus (HBV) or hepatitis C virus (HCV) are important risk factors for the development of HCC (122-124). Infection with HBV early in life appears to be a much stronger risk factor for HCC than acquisition of HBV in adulthood (121). Studies in China found that 40% of babies born to mothers who carried HBV also became infected with HBV, leading to public health efforts to interrupt the chain (125). Chronic infection with HBV has been associated with HCC even in the absence of detectable serum HbsAg (126). It has been suggested that the use of a hepatitis B virus vaccine, which provides durable immunity in very young children, will probably prevent most cases of HCC (127). Vaccination against HBV is currently recommended for all children in the United States (128;129).

Worldwide, exposure to aflatoxins is also a major risk for HCC (130). This risk may be modulated by both genetic factors (which may be increased in some ethnic groups) and environmental factors (such as infection with HBV) (130-132).

HCC incidence in the United States has recently been rising (133), with HCV the suspected cause (134). Recently reported findings from a prospective cohort study in New Jersey of HCV-infected men and women found an increased risk of 9.7 fold compared to expected (based on New Jersey HCC yearly incidence data, by age, gender, and race) (70). These New Jersey data are believed to be the first prospective data from the United States supporting an increasing risk for HCC and an apparent link with HCV (70).

HCV is believed to have spread extensively among injection drug users (IDUs) in the United States during the 1970s and early 1980s, with particularly high rates in New Jersey that reach 99% in one statewide cohort (135). In addition to the HCC risk, HBV and HCV are also associated with substantial morbidity and mortality, with liver failure accounting for 10% of the deaths among IDUs (for both human immunodeficiency virus [HIV] negative and positive persons)

(135;136). HBV and HCV are also related to progressive liver disease in persons with blood product-related acquisition (e.g., hemophiliacs and persons receiving blood products prior to implementation of effective screening) (137;138). In the United States, about 2.7 million persons are chronically infected with HCV (139). Among United States' patients undergoing liver transplantation, HCV is currently the leading cause of liver failure. People who use illegal drugs or engage in high-risk sexual behavior account for most of those currently infected with HCV in the United States (139). However, tattooing and body piercing are risk factors for HBV and HCV (140), as well as other parenterally transmissible pathogens such as human immunodeficiency virus (HIV). HIV infection appears to worsen this natural history of chronic parenterally acquired hepatitis C, leading to an unusually rapid progression to cirrhosis (141;142).

Studies from Japan have led to estimates that the average time from initial infection with HCV until the development of HCC likely exceeds 20 to 30 years. Thus, the above data from New Jersey are likely the first harbingers of a forthcoming rapid and significant rise in the number of new HCC cases in our state, as well as globally, over the next one to two decades.

In 1988, the New Jersey Commission on Cancer Research urged primary care physicians to consider the emerging role of prevention strategies in hepatocellular carcinoma (143). These data reinforce the importance of prevention measures, including the primary prevention approach of vaccination.

Future steps in liver cancer should include: continuing support for vaccination of New Jersey children against HBV in accordance with CDC guidelines; increasing efforts to identify and vaccinate adults at risk for HBV and HCV; continuing epidemiologic studies examining HCC risk and efforts to explore whether there are predictive markers or co-factors amongst HCV-infected persons; monitoring HCC incidence trends in New Jersey; encouraging clinical trials that seek to improve survival in persons diagnosed with HCC; and considering establishing regulations to reduce HBV, HCV, and retroviral transmission that can occur in establishments engaged in tattooing, body piercing, or similar practices (144;145).

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CHAPTER 14. Implementation

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IMPLEMENTATION

The next step for the *New Jersey Comprehensive Cancer Control Plan* is implementation. Submission of the Task Force report to the Governor benchmarks not the end of the process but rather a beginning. Critical to the success of implementation will be the essential elements as identified by the Implementation Ad Hoc Committee and briefly discussed below – assessment, funding, and coordination.

ASSESSMENT

Although some new programs and services may arise from recommendations of the Task Force on Cancer Prevention, Early Detection and Treatment in New Jersey, comprehensive cancer control planning is not only about creating new programs and services, but also first and foremost about coordinating and integrating what is already there. New Jersey is fortunate to have many resources to draw upon, and the Task Force and its workgroups and subcommittees have spent many months familiarizing themselves with some of these resources. However, a number of recom-mendations in the *Plan* address the importance of learning what capacity currently exists throughout the state – and where the need for services is greatest – before forging ahead to develop new programs. Without a baseline capacity and needs assessment, we run the risk of overlooking major gaps in some parts of the state and of duplicating efforts in other parts of the state.

North Carolina, one of the earliest states to develop and implement a comprehensive cancer control plan, recognized that a comprehensive inventory would promote information sharing and communication among diverse groups (1). Conducting a Capacity and Needs Assessment should thus be an early step in the implementation process. A Capacity and Needs Assessment will provide information on the best approach to implementing the *Plan*, help keep the implementation process on target, and provide both baseline and (over time) follow-up information for evaluation purposes (2).

Conducting a Capacity and Needs Assessment will bring together the efforts of both public and private agencies that have already begun to inventory the many cancer control activities in our state. From this baseline, ongoing identification of organizations and programs and a dissemination of the information will be undertaken. Individual capacity and needs assessment strategies have been built into separate chapters of the *Comprehensive Cancer Control Plan*. However, by designating assessment as an overall implementation strategy and setting it as our first implementation objective, we stress the importance the Task Force assigns to developing a centralized cancer resource for New Jersey's many constituents.

FUNDING

Funding sources are extremely critical to successful implementation. The Imple-mentation Ad Hoc Committee recommends that an action group be dedicated to identifying and obtaining funding for plan implementation, as well as for administrative support to further this initiative. However, as the Centers for Disease Control and Prevention (CDC) points out in its *Guidance Document*, this ongoing activity of mobilizing support involves more than merely securing funding. It requires a broad campaign that will provide visibility, develop political good will, and enhance awareness of community leaders who may become advocates for both

funding and implementing portions of the *Plan* (2).

COORDINATION

Finally, all of these efforts cannot be accomplished without coordination and communication. Designating an agency to coordinate and monitor plan implementation is one of the CDC building blocks for comprehensive cancer control that become the foundation for implementing the plan and institutionalizing the initiative (2). The coordinating agency will facilitate the process of achieving unity of effort among diverse participants and diverse activities so that the goals and objectives in the *Plan* are attained (3). Successful implementation will depend on effective coordination and communication among the many committed organizations and the myriad rich resources here in New Jersey. The Implementation Ad Hoc Committee recognizes the many facets necessary for coordination. Committee members further believe that internally monitoring plan implementation and communicating with partners about programs, resources, and best practices through multiple media will assist in guiding joint efforts and benchmarking progress. Coordination and communication will not only foster synergy among the stakeholders but will also ultimately benefit all the citizens of New Jersey through enhanced cancer prevention and control.

The Task Force on Cancer Prevention, Early Detection and Treatment and its workgroups and subcommittees has developed a culturally sensitive plan for state-level action on cancer prevention and control that encompasses prevention, early detection, treatment, rehabilitation, palliation, and quality of life issues and will embrace all New Jerseyans. Recognizing that coalition building, partnerships, and education are essential to fruition of the *Plan*, the Implementation Ad Hoc Committee presents the following goal, objectives, and strategies for implementation.

GOALS, OBJECTIVES AND STRATEGIES

GOAL IM-1:

To implement the *New Jersey Comprehensive Cancer Control Plan.*

Objective IM-1.1:

To conduct a Cancer Capacity and Needs Assessment for New Jersey.

Strategies:

- (IM-1.1.1) Identify and develop a database inventory of those organizations and programs that engage in or support cancer control-related activities.
- (IM-1.1.2) Partner with key stakeholders to identify gaps in cancer control-related program and activities.
- (IM-1.1.3) Disseminate results of the Capacity and Needs Assessment using multiple media, especially the internet.

Objective IM-1.2:

To identify funding streams for implementation of the *New Jersey Comprehensive Cancer Control Plan*.

Strategies:

- (IM-1.2.1) Create a Funding and Resources Action Group to identify and obtain funding for the *New Jersey Comprehensive Cancer Control Plan*.
- (IM-1.2.2) Establish a funded, state-level grant-writing position to pursue funding opportunities for the *New Jersey Comprehensive Cancer Control Plan*.

Objective IM-1.3:

To coordinate and mobilize key stakeholders for implementation of the *Plan*.

Strategies:

- (IM-1.3.1) Transition Task Force workgroups and subcommittees into Action Groups.
- (IM-1.3.2) Empower Action Groups to prioritize strategies and obtain commitments from respective organizations and agencies.

Objective IM-1.4:

To develop a framework for the assessment of progress made toward achievement of goals, objectives, and strategies for the *New Jersey Comprehensive Cancer Control Plan*.

Strategies

- (IM-1.4.1) Internally monitor implementation activities of the Action Groups.
- (IM-1.4.2) Share programs, resources, and best practices through such means as a newsletter, website, and/or annual conference.
- (IM-1.4.3) Based on evaluation of implementation activities, provide for review and revisions and initiate the next planning cycle.

Objective IM-1.5:

To plan and coordinate a rollout campaign for the *New Jersey Comprehensive Cancer Control* Plan.

Strategies:

- (IM-1.5.1) Work with the Office of the Governor and the Office of Communications in the New Jersey Department of Health and Senior Services on a statewide rollout campaign to include plan presentation, recognition of participants, and public acknowledgement of the commitment of participants.
- (IM-1.5.2) Honor survivors and memorialize those who have been part of the battle against cancer in New Jersey.

- (IM-1.5.3) Investigate further solicitation of agencies for partnering with the *New Jersey Comprehensive Cancer Control Plan* through strategies such as an implementation website.

Principal Change Agents: The following organizations will contribute to the implementation of strategies shown. This list is not mutually exclusive.

New Jersey Department of Health and Senior Services: IM-1.1.1; IM-1.1.2; IM-1.1.3; IM-1.2.1; IM-1.2.2; IM-1.3.1; IM-1.3.2; IM-1.4.1; IM-1.4.3; IM-1.5.1; IM-1.5.2; IM-1.5.3
New Jersey Department of Health and Senior Services, Office of Cancer Control and Prevention: IM-1.1.1; IM-1.1.2; IM-1.1.3; IM-1.3.1; IM-1.3.2; IM-1.4.1; IM-1.4.2; IM-1.4.3; IM-1.5.1; IM-1.5.2; IM-1.5.3

IMPLEMENTATION

GOAL	OBJECTIVE	STRATEGY	2003	2004	2005	2006	2007	On-going
1: Implement the Comprehensive Cancer Control Plan	1.1: Conduct capacity and needs assessments	IM-1.1.1	■	■	■	■	■	■
		IM-1.1.2	■	■	■	■	■	■
		IM-1.1.3	■	■	■	■	■	■
	1.2: Identify funding streams	IM-1.2.1	■					
		IM-1.2.2	■					
	1.3: Coordinate/mobilize key stakeholders	IM-1.3.1	■					
		IM-1.3.2	■					
	1.4: Develop framework for assessment	IM-1.4.1	■	■	■	■	■	■
		IM-1.4.2	■	■	■	■	■	■
		IM-1.4.3	■	■	■	■	■	■
	1.5: Plan/coordinate rollout campaign	IM-1.5.1	■					
		IM-1.5.2						
		IM-1.5.3						

■ **Target Completion Date**

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CHAPTER 15. Evaluation

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EVALUATION

Evaluation is critical to ongoing success and utility of the *New Jersey Comprehensive Cancer Control Plan.* Charged by Executive Order 114, the Task Force on Cancer Prevention, Early Detection and Treatment in New Jersey is responsible not only for reporting initial findings to the Governor, but thereafter for submitting biennial reports (1). Recognizing the importance of obtaining data on implementation progress over time for the biennial reports to the Governor, the Task Force charged an Ad Hoc Committee with development of an Evaluation Chapter for the *Plan*. In preparing this chapter, the Committee reviewed best practices by the comprehensive cancer control model planning states and the comprehensive cancer control implementation grantees funded by the Centers for Disease Control and Prevention (CDC), especially the states of Kentucky, Maine, Michigan, and North Carolina. The Committee also considered recommendations by Battelle Centers for Public Health Research and Evaluation, a consultant to the Task Force throughout the planning process.

The conceptual model developed by Battelle for CDC's Division of Cancer Prevention and Control presents an outcomes-based planning and implementation process, the long-range goal of which is to achieve significant reductions in the incidence, morbidity, and mortality of cancer among all citizens (2). In this model, Evaluation is considered as one of the six "building blocks" of comprehensive cancer control – needed to monitor progress and record results for accountability purposes, but also to identify problems and facilitate ongoing program improvement. Following this model, New Jersey has built evaluation into its *Plan* to assist Task Force members in visualizing what success will look like and in documenting that success over time. Evaluation has been part of New Jersey's planning process from the outset. For example, evaluation activities were conducted after each Task Force and workgroup meeting to benchmark participant satisfaction and to guide "continuous quality improvement" in process and procedures.

CDC and Battelle recommend evaluating the comprehensive cancer control process as a whole as well as each respective phase – planning, implementation, and institutionalization – while also preparing to measure long-term health outcomes. Comprehensive cancer control is a highly complex and dynamic initiative, and many of its outcomes are relatively intangible and difficult to "measure", such as improved working relationships among partners (2). Attempting to measure health outcomes prematurely (such as decreases in morbidity and mortality or reductions in disparities) can lead to disappointing results. While the health outcomes remain always in view as the ultimate outcome desired, they will not be achieved until some years hence. Task Force efforts are currently concentrated on building an implementation infrastructure able to put into action the statewide cancer plan that New Jersey cancer experts believe will lead to the desired health outcomes. It is documenting success in this aspect of the endeavor that should be the initial evaluation focus, while systems are established to eventually measure long-term health outcomes.

A number of states have already developed feasible approaches to evaluating their comprehensive cancer control initiatives. North Carolina, for example, recognized the critical need for evaluation in its 1996 – 2001 *Plan* and realized that without monitoring and documentation, the effectiveness of their efforts would be unknown, state resources would be less than wisely utilized, and the

development of future plans might be hindered (3). Michigan, in the case study of their comprehensive cancer control planning process, set short- and long-term goals to assess outcomes of the implementation process, while monitoring the process as a whole in an ongoing manner (4).

Availability of adequate evaluation data is critical for the effective implementation of the *New Jersey Comprehensive Cancer Control Plan*, as well as for the development of future plans (3). While the Ad Hoc Committee realizes that incidence and mortality change is a long-term goal, measurement of the ongoing process to achieve that change is also essential.

The Evaluation Ad Hoc Committee has determined that convening an Evaluation Planning Workgroup and identifying and securing funding for evaluation represent critical first steps in developing an evaluation strategy for the New Jersey comprehensive cancer control process. The Committee also recognized the importance of utilizing an outside agency to develop and implement an Evaluation Plan, based on the experiences of the New Jersey Comprehensive Tobacco Control Program. CDC concurs that monitoring progress and measuring outcomes against plan goals, objectives, and strategies may require the services of a professional evaluator (5).

Below the goal, objective, and strategies developed by the Task Force's Evaluation Ad Hoc Committee to initiate development of an evaluation design for New Jersey's comprehensive cancer control process are presented.

GOALS, OBJECTIVES AND STRATEGIES

GOAL EV-1:

To evaluate the *New Jersey Comprehensive Cancer Control Plan* by assessing the implementation and effectiveness of its strategies, by determining its impact on the knowledge and behavior of the citizens of New Jersey, and by measuring resultant changes in health outcomes.

Objective EV-1.1:

To develop and implement an Evaluation Plan for the *New Jersey Comprehensive Cancer Control Plan*.

Strategies:

- (EV-1.1.1) Identify members of an Evaluation Planning Workgroup.
- (EV-1.1.2) Identify and secure funding for evaluation of the *Plan*.
- (EV-1.1.3) Identify, through an RFP process, a New Jersey academic institution to develop and implement an Evaluation Plan in partnership with the Task Force on Cancer Prevention, Early Detection and Treatment in New Jersey.

Principal Change Agents: The following organizations will contribute to the implementation of strategies shown. This list is not mutually exclusive.

Task Force on Cancer Prevention, Early Detection and Treatment in New Jersey, Evaluation Ad Hoc Committee: EV-1.1.1; EV-1.1.2; EV-1.1.3
University of Medicine and Dentistry of New Jersey – School of Public Health: EV-1.1.3

EVALUATION

GOAL	OBJECTIVE	STRATEGY	2003	2004	2005	2006	2007	On-going
1: Evaluate the Comprehensive Cancer Control Plan	1.1: Develop/implement an Evaluation Plan	EV-1.1.1	■					
		EV-1.1.2						
		EV-1.1.3		■				

■ Target Completion Date

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